

packaged *methamphetamine hydrochloride tablets* failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: November 10, 1953. The defendant having entered a plea of nolo contendere, the court fined it \$500.

4248. Misbranding of dextro-amphetamine sulfate tablets, methyltestosterone tablets, tablets containing a mixture of pentobarbital and aspirin, and liquid mixture containing, among other things, phenobarbital. U. S. v. Robert T. Royce (Royce Drug Store), and Aubrey E. Simmons. Plea of nolo contendere by Defendant Royce and plea of guilty by Defendant Simmons. Fine of \$120 against Defendant Royce and \$105 against Defendant Simmons. (F. D. C. No. 32734. Sample Nos. 15446-L to 15448-L, incl., 15450-L, 16451-L, 16453-L, 16456-L, 16458-L.)

INFORMATION FILED: September 18, 1952, Western District of Oklahoma, against Robert T. Royce, trading as the Royce Drug Store, Lawton, Okla., and Aubrey E. Simmons, a pharmacist in the store.

ALLEGED VIOLATION: On or about October 11, 13, 15, and 22, 1951, while a number of *dextro-amphetamine sulfate tablets, methyltestosterone tablets, tablets containing a mixture of pentobarbital and aspirin, and liquid mixture containing, among other things, phenobarbital* were being held for sale at the Royce Drug Store, after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the dispensed drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), all of the repackaged drugs failed to bear a label containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), the repackaged drugs, with the exception of the *tablets containing a mixture of pentobarbital and aspirin* and a portion of the *liquid mixture containing, among other things, phenobarbital*, failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the repackaged *tablets containing a mixture of pentobarbital and aspirin* and the repackaged *liquid mixture containing, among other things, phenobarbital* were drugs for use by man and contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the label of such drugs failed to bear the name, and quantity or proportion of such derivatives and in juxtaposition therewith a statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), a portion of the repackaged *dextro-amphetamine sulfate tablets* and all of the *methyltestosterone tablets* failed to bear a label containing the common or usual name of each active ingredient of the drugs.

DISPOSITION: On November 21, 1952, upon a plea of nolo contendere by Defendant Royce, the court fined him \$120. On April 2, 1954, upon a plea of guilty by Defendant Simmons, the court fined him \$105.